memorandum (Opp. Mem. at 49), even though that section does not point to *any* allegations specific to NPC. In short, the States do not deny that they have not pled such specifics as to NPC, including, fundamentally, ***how*** NPC allegedly misstated Best Price. The States thus do not, and cannot, dispute that they nowhere plead how or to whom NPC allegedly provided free samples of drugs, volume discounts, rebates, education grants, or allegedly engaged in any other conduct that purportedly resulted in misreporting to the Medicaid program or even that NPC has been the subject of any government inquiry relating to Best Price fraud. Nor do the States contest that none of the alleged "exemplary misconduct" pled (Mont. Cplt. ¶616-33; Nev. Cplt. ¶ 397-403) involves NPC. Thus, in the absence of even a single specific example in connection with the alleged Best Price scheme relating to NPC, the States' general allegations of industry-wide behavior fail to meet the requirements of Fed. R. Civ. P. 9(b) and 12(b)(6) as to NPC. *See also* Defendants' Consolidated Reply Memorandum, Point I.C.

## IV. NEVADA DOES NOT PLEAD SPECIFIC FACTS AS TO ITS RACKETEERING CLAIM THAT SATISFY FED. R. CIV. P. 9(b) OR 12(b)(6).

Nevada's Count IV racketeering claim, which also is subject to Fed. R. Civ. P. 9(b) pleading mandate (NPC Mem. at 5), relies upon the same general allegations as the States' other AWP- and Best Price- related claims. For all of the same reasons set forth above in Points II and III, Nevada thus fails to plead racketeering predicate acts as to NPC with the specificity required and otherwise fails to state a claim upon which relief may be granted. The racketeering claims also must be dismissed because Nevada lacks standing to bring such claims and fails to allege a cognizable enterprise. Defendants' Consolidated Reply Memorandum, Point II.B.

## CONCLUSION

For the foregoing reasons, as well as those set forth in the moving memoranda and defendants' consolidated and individual reply memoranda, the Court should dismiss with prejudice all claims as to NPC.

Dated: Boston, Massachusetts
November 7, 2003

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**#12**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | M.D.L. No. 1456<br>Civil Action No. 01-12257-PBS<br>Judge Patti B. Saris |
| THIS DOCUMENT RELATES TO:<br>*State of Montana v. Abbott Labs, Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM<br>*State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR | |

**INDIVIDUAL REPLY MEMORANDUM OF PFIZER INC. IN SUPPORT OF ITS MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND STATE OF NEVADA'S AMENDED COMPLAINT**

Plaintiffs' response to Pfizer's opening memorandum is revealing as much for what it does not say as for what it says. First, Pfizer's opening memorandum pointed out that plaintiffs' complaints allege no specific fraudulent conduct by Pfizer with respect to AWPs. In response, plaintiffs rely entirely on "pages of allegations documenting an industry-wide practice of creating fraudulent AWPs." Pl. Specific Opp., p. 49. Thus, plaintiffs do not even argue that they have pleaded AWP fraud with particularity as to Pfizer. Rather, they argue that they should be excused from doing so, and be permitted to lump Pfizer into this case without differentiation.

Second, Pfizer's opening memorandum pointed out that plaintiffs' complaints allege no specific fraudulent conduct by Pfizer with respect to best price. In response, plaintiffs argue only that they "have set forth the general allegations as to the Best Price scheme," and that they should be permitted to take discovery to go further. Pls. Specific Opp., p. 49. Thus, as with the AWP claims, plaintiffs seek to lump Pfizer together with other defendants and be excused from pleading best price fraud with particularity as to Pfizer.

Finally, Pfizer's opening memorandum pointed out that plaintiffs' Medicaid allegations regarding multi-source drugs are economically irrational. Rather than squarely address this point, plaintiffs try to recast their allegations and change their theory.

For these reasons, as discussed more fully below, plaintiffs' claims against Pfizer should be dismissed.

## I. PLAINTIFFS HAVE NOT PLEADED PFIZER'S ALLEGED FRAUD WITH PARTICULARITY.

Plaintiffs concede that they must "clearly identify … the fraud being perpetrated by defendants with respect to the designated drugs." Pl. Specific Opp., p. 5. Since they are unable to meet this requirement, plaintiffs contend that Pfizer demands quantification of the damages for every transaction for every drug. What Pfizer (and more importantly, Rule 9(b)) demands is particularized allegations of fraudulent conduct by Pfizer. Plaintiffs merely list the AWP for several Pfizer drugs, repeat their incantations about an industry-wide scheme, and leave it to the Court to assume some fraudulent conduct by Pfizer.

The cases cited by plaintiffs involve single defendant groups, and therefore do not apply here. *See In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. LEXIS 7400 at * 7-8 (D. Mass. Mar. 8, 2002) (securities fraud suit against corporation and executives); *Kuney Int'l, S.A. v. Dilanni*, 746 F. Supp. 234, 237 (D. Mass. 1990) (suit against investment company and its principals). Having chosen to bring a multi-defendant case, plaintiffs must provide particularity as to each defendant. Plaintiffs' undifferentiated references to "defendants' are not sufficient.

## II. PLAINTIFFS' CLAIMS ABOUT MULTIPLE-SOURCE DRUGS ARE INSUFFICIENT.

As Pfizer's opening memorandum demonstrated, plaintiffs' best price fraud claims are economically irrational as applied to multiple-source drugs. Plaintiffs try to avoid this quandary by recasting their complaint as focusing only on those multiple-source drugs "where the rebate is tied to single source drugs and innovator multiple source drugs." Pl. Specific Opp., p. 16. On one hand, plaintiffs argue that their fraud allegations are sufficient because they apply to all drugs and the entire industry. Pl. Specific Opp., p. 16-17. On the other, plaintiffs concede that some drugs are not subject to the alleged industry-wide fraud. Plaintiffs' position is internally inconsistent, and their effort to keep multiple source drugs in this case should be rejected.

## III. THE BEST PRICE CLAIMS ARE INSUFFICIENTLY PARTICULAR TO AVOID DISMISSAL.

Unable to point to a single particularized instance of best price fraud by Pfizer, plaintiffs claim that they have set forth general allegations as to the best price scheme. What Plaintiffs have not done is to set forth facts showing that Pfizer participated in this alleged scheme.[1/] Plaintiffs merely reveal the weakness of their allegations by requesting discovery from Pfizer to bolster their unsupported claims. Pfizer should not be subject to discovery concerning claims that should not have been brought in the first place.

## IV. CONCLUSION

For the foregoing reasons, Pfizer should be dismissed from this action.

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1/ Plaintiffs' reference to the Lipitor settlement is insufficient to satisfy Rule 9(b). First, the complaints allege no conduct specific to that drug. Second, Pfizer's decision to settle – without admitting any wrongdoing – a Best Price claim under a federal enforcement statute proves nothing relevant to this case. Finally, a passing reference to the Lipitor settlement is not sufficient to support Plaintiffs' far-reaching allegation that every Best Price report submitted by Pfizer for all of its products were fraudulent.

Respectfully submitted,

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Dated: November 7, 2003

**#13**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | M.D.L. No. 1456<br>Civil Action No. 01-12257-PBS<br>Judge Patti B. Saris |
| THIS DOCUMENT RELATES TO<br>*State of Montana v. Abbott Labs, Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM | |

**INDIVIDUAL MEMORANDUM OF PHARMACIA CORPORATION AND PHARMACIA & UPJOHN, INC. IN SUPPORT OF MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

In its opening memorandum, Pharmacia demonstrated that (1) plaintiff has failed to allege any fraudulent conduct with respect to Celebrex; (2) plaintiff's claims regarding multiple-source drugs are economically irrational; and (3) plaintiff has failed to allege any particularized fraudulent Best Price conduct by Pharmacia. Unable to refute these arguments, plaintiff either mischaracterizes or ignores them.

## I. MONTANA HAS NOT PLEADED ANY FRAUDULENT CONDUCT RELATED TO CELEBREX.

Plaintiff does not cite a single paragraph of its complaint that specifically alleges fraudulent conduct relating to Celebrex. For this reason alone, plaintiff's claims respecting Celebrex should be dismissed. Plaintiff also has alleged no AWP spread for Celebrex. Thus, the only specific allegation about Celebrex is that it had a published AWP. This allegation does not meet Rule 9(b).

## II. MONTANA'S MULTIPLE-SOURCE DRUG CLAIMS ARE INSUFFICIENT.

Similarly, plaintiff fails to address Pharmacia's argument that its claims related to multiple-source drugs are economically irrational. *See* Plaintiff's Response, p. 52. Moreover, plaintiff does not address its failure to identify with particularity which drugs are subject to its fraud claims. Instead, plaintiff suggests that, as the manufacturer, Pharmacia must know. *Id.* This circular reasoning fails to show fraud as to particular drugs. Accordingly, the Court should dismiss all claims related to multi-source drugs.

## III. MONTANA ALLEGES NO FRAUDULENT "BEST PRICE" ACTIVITY BY PHARMACIA.

Rather than address its failure to allege specific fraudulent best price activity by Pharmacia, plaintiff seeks to mischaracterize the issue, suggesting that Pharmacia is seeking to require "the listing on a day-by-day basis, either (1) purchases at a lower price, or (2) specific sale [sic] improperly excluded from AMP." *Id.* Pharmacia made no such argument. Rather, Pharmacia argues that this Court's May 13 Order requires plaintiff to plead fraud on a drug-by-drug basis. Plaintiff does not contest that this is required, or that it has failed to meet this requirement. Instead, plaintiff again argues, in essence, that Pharmacia knows what it did. *Id.* at 52-53. Thus, plaintiff seeks to avoid its pleading burden entirely. Plaintiff has not alleged a single best price related activity by Pharmacia, and these claims should be dismissed.

## IV. CONCLUSION

For these reasons, plaintiff's claims against Pharmacia should be dismissed.

Respectfully submitted,

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Dated: November 7, 2003

**#14**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL No. 1456 |
| | Civil Action No. 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR; *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM | Judge Patti B. Saris |

**REPLY MEMORANDUM OF SCHERING-PLOUGH CORPORATION IN SUPPORT OF THE MOTIONS TO DISMISS**

The States have attempted to plead a case of fraud against Schering-Plough Corporation ("Schering") based on nothing more than allegations of an industry-wide "AWP Inflation Scheme" and a list of published Schering AWPs. The "general outline" on which the States rely in the Amended Complaints does not identify any fraudulent conduct by Schering. *See* Mont. Cplt. ¶¶ 175-184, 201-209; Nev. Cplt. ¶¶ 138-147, 164-172. Moreover, the targeted "Schering-Plough Group" allegations fail to offer even one specific example of fraudulent conduct by Schering. *See* Mont. Cplt. ¶¶532-549; Nev. Cplt. ¶¶ 333-350. The States thus ask this Court to infer from *nothing more than the act of reporting AWPs* that Schering may have defrauded the States on the reimbursement of every one of its branded drugs. Of course, every drug manufacturer reports AWP. *See* Mont. Cplt. ¶ 166; Nev. Cplt. ¶ 129. The States cannot satisfy Rule 9(b) simply by pointing to such ubiquitous behavior and on that basis lumping Schering together with other defendants under general allegations of a "fraudulent scheme." *See Jepson,*

*Inc. v. Makita Corp.*, 34 F.3d 1321, 1326 (7th Cir. 1994) (Rule 9(b) requires separate allegations for separate defendants); *Hayduk v. Lanna*, 775 F.2d 441, 444 (1st Cir. 1985).

In their Opposition to the Defendant-Specific Memoranda on Motions to Dismiss ("Opposition"), the States attempt to obscure the Amended Complaints' failure to specify any fraudulent conduct associated with Schering's branded drugs by pointing to Warrick Pharmaceutical Corporation's ("Warrick") conduct relating to its multi-source drugs.[1] *See* Opposition at 53-55; Mont. Cplt. ¶¶ 532-549; Nev. Cplt. ¶¶ 333-350. The States improperly seek to rely on "anecdotal examples of AWP price spreads" for Warrick to provide "precision and substantiation" of alleged fraud by Schering. Opposition at 6-8, 55. The mere statement of "anecdotal" "spreads" for some other manufacturer – even one that is a wholly-owned subsidiary of Schering – does not suffice to plead with particularity a claim against Schering under Rule 9(b). *See Jepson, Inc.*, 34 F.3d at 1324, 1326, 1328-1329 (plaintiffs must distinguish in fraud allegations between parent and wholly-owned subsidiary).

The States have pled nothing more with regard to Schering's conduct than its mere reporting of AWPs – an activity in which every drug manufacturer engages. There is thus no basis for this case to proceed against Schering.

[1] The States misleadingly claim in their Opposition that "Schering was out marketing spreads of 2,082%, 757%, and 460%." Opposition at 55. In the Amended Complaints, these alleged "spreads" are associated with Warrick's drugs ISMN, oxaprozin, and potassium chloride, respectively. *See* Mont. Cplt. ¶ 540; Nev. Cplt. ¶ 341. No "spreads" have been alleged for any of Schering's drugs.

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Dated: November 7, 2003

CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2003, I caused a true and correct copy of the Reply Memorandum of Schering-Plough Corporation in Support of the Motions to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien

**#15**

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456 |
| THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Laboratories, Inc., et al.*, 02-CV-12086-PBS | CIVIL ACTION: 01-CV-12257-PBS<br>Judge Patti B. Saris |

**TAP PHARMACEUTICAL PRODUCTS INC.'S SEPARATE REPLY IN SUPPORT OF ITS MOTION TO DISMISS MONTANA'S SECOND AMENDED COMPLAINT**

## I. Montana Alleges No Fraudulent Conduct By TAP Regarding Prevacid®

Montana's Complaint contains no specific allegations regarding Prevacid®, which is the only TAP drug identified in the Complaint. Instead, Montana spends four pages of its Complaint describing alleged conduct exclusively relating to Lupron®, a drug that is not a subject of Montana's lawsuit. In its opposition, Montana spends yet another page describing alleged conduct exclusively relating to Lupron®. Conspicuously absent, again, are any allegations relating to Prevacid®.

In its response, Montana concedes that it cannot allege any specific facts regarding Prevacid®. Instead, Montana contends that it "identif[ies] the corporate climate and industry with respect to AWP manipulation practices" at TAP. Pl. Sep. Mem. at 57. Montana makes no excuse for its failure to mention TAP and Prevacid® in connection with the Medicaid rebate claims.

Montana's misguided allegations are facially inadequate. Because Montana offers no allegations at all regarding Prevacid®, the Complaint cannot survive as to TAP. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (hereinafter "*AWP Litigation*"). By relying solely on a so-called "corporate climate" of fraud, Montana admits as much. Accordingly, Montana's Complaint should be dismissed as to TAP under Rules 9(b) and 8(a) for failure to allege fraudulent conduct relating to Prevacid®.

## II. Montana Does Not Explain How AWP Manipulation Can Create A Competitive Advantage For Prevacid®

Likewise, Montana's Complaint should be dismissed under Rules 9(b) and 8(a) for failure to explain how TAP could gain a competitive advantage by manipulating the AWP for Prevacid®. As explained more fully in TAP's motion to dismiss the AMCC, Montana's theory of AWP manipulation requires that three factors be present:

1. A competitive, therapeutic equivalent must exist.

2. The provider who chooses the drug must receive payment directly.

3. The payment for the two competing drugs must be based upon each drug's individual AWP. *See* 42 C.F.R. § 405.517(b).

If any one of these factors is absent, plaintiffs' theory makes no economic sense and should be dismissed. *See, e.g., Interface Group, Inc. v. Massachusetts Port Auth.*, 816 F.2d 9, 12 (1st Cir. 1987).

Here, Montana does not allege facts to establish the first two elements. First, Montana fails to allege that a competitive therapeutic equivalent to Prevacid® exists. Without such a therapeutic equivalent, TAP could not have competed on the spread as Montana suggests. Second, Montana fails to allege that the provider who chooses Prevacid® actually receives payment for it. Prevacid® is a pill that physicians prescribe, but that pharmacists dispense.

Montana argues in its Opposition that Rule 9(b) does not require it to allege competitors for all of defendants' drugs. Pl. Sep. Mem. at 57. TAP, of course, is not suggesting that Montana name competitors for all of defendants' drugs. The very nature of multiple-source drugs implies the existence of competitors. Montana must, however, identify a competitor for single-source drugs, like Prevacid®. Otherwise, the scheme alleged in the Second Amended Complaint does not make economic sense. *See Interface*, 816 F.2d at 12 (affirming dismissal of complaint in absence of any economic incentive for defendant from alleged antitrust violation). Montana's complaint must be dismissed for failure to allege how Prevacid® competed on the "spread."

## III. Montana Does Not Dispute That The Complaint Should be Dismissed Against TAP Under Rule 12(b)(5)

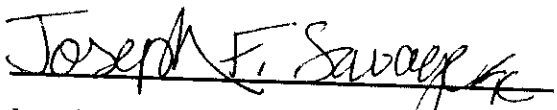
Montana does not dispute that TAP has never been served in this case. Accordingly, TAP should be dismissed from the Complaint under Rule 12(b)(5).

## IV. Conclusion

For the foregoing reasons, as well as those stated in the Consolidated Memorandum, TAP's Separate Memorandum of Law in Support of its Motion to Dismiss the AMCC, and those individual defendants' memoranda that apply to TAP, this Court should dismiss Montana's Second Amended Complaint as to TAP.

Respectfully Submitted,

Dated: November 7, 2003



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**#16**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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|---|---|
| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL No. 1456 |
| | Civil Action No. 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR; *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM | Judge Patti B. Saris |

**REPLY MEMORANDUM OF WARRICK PHARMACEUTICALS CORPORATION IN SUPPORT OF THE MOTIONS TO DISMISS**

The multi-source market simply does not fit the paradigm alleged in the States' Amended Complaints. The States have not explained – and cannot explain – how, if Warrick raised the published AWP of one of its multi-source drugs, Warrick could have gained a competitive advantage for itself. According to the Amended Complaints, Medicare reimburses a Warrick drug at the lesser of the median AWP of all generic forms of the drug or the lowest AWP of the brand name product. The States reimburse at 150% of the single lowest published AWP for the drug (the "FUL"). *See* Mont. Cplt. ¶¶ 187-188; Nev. Cplt. ¶¶ 150-151. Private payors, for their part, at times reimburse Warrick's multi-source drugs based on MACs, which, in turn, are "based upon the FULs." Mont. Cplt. ¶¶ 193-194; Nev. Cplt. ¶¶ 156-157. Under these reimbursement schemes, raising the AWP of a Warrick drug could not affect the reimbursement amount for that drug relative to its competitors. Thus Warrick simply could not have engaged in the fundamental wrongdoing alleged throughout the Amended Complaints – namely, "push[ing] market share" of

a drug by "increasing [its] published AWP." Mont. Cplt. ¶¶ 176-180, 185-209; Nev. Cplt. ¶ 139-143, 148-172.

Montana also alleges that "if a generic drug does not have at least three suppliers, the reimbursement amount is AWP less 15%." Mont. Cplt. ¶ 188. But it cannot be determined from Montana's Second Amended Complaint whether *any* of Warrick's drugs are reimbursed by Montana Medicaid at AWP less 15%, rather than the median AWP or the FUL. Nor do the States' Amended Complaints identify with specificity any Warrick drug for which private payors reimbursed at "a certain percentage 'discount' off AWP," as opposed to a MAC. Mont. Cplt. ¶ 193; Nev. Cplt. ¶ 156. In short, the States do not identify a single Warrick drug that is reimbursed based on an AWP reported by Warrick, and certainly do not offer a single specific example of Warrick gaining a competitive advantage by inflating the AWP of one of its drugs. Without even one such example, the States' general allegation that all drugs are subject to competition based on AWP inflation in all contexts is insufficient to satisfy Rule 9(b). *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147-148 (D. Mass. 2000).

Moreover, the States' allegation of various "anecdotal" "spreads" cannot suffice to state a claim. At most, the alleged "spreads" establish that Warrick's multi-source drugs compete vigorously on price and may be subject to significant discounts. This Court has already rejected the private plaintiffs' attempt to rely on the existence of "spreads" to prove fraud. *See In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). The Court should reject the States' attempt to do so here.

Warrick could not have garnered for itself a competitive benefit even if it had engaged in the fundamental wrongdoing alleged in the Amended Complaints. All claims against Warrick should be dismissed.

Respectfully Submitted,

/JRT

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Dated: November 7, 2003

CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2003, I caused a true and correct copy of the Reply Memorandum of Warrick Pharmaceuticals Corporation in Support of the Motions to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien